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EXAMINER

LIN, JERRY

ART UNIT	PAPER NUMBER
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1631

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/27/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

DETAILED ACTION

1. Applicants' arguments, filed November 11, 2006, have been fully considered and they are not deemed to be persuasive. The following rejections are either reiterated or newly applied as necessitated by amendment. They constitute the complete set presently being applied to the instant application.

Election/Restrictions

2. Newly submitted claims 21-23 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons:

The elected group is related to the new claims as a product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the product may be used to monitor the ambient temperature.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 20-23 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Status of the Claims

Claims 1-3, 5-13 and 20 are under examination.

Claims 14-19 and 21-23 are withdrawn as being drawn to an unelected invention.

Claim Rejections - 35 USC § 112, 2nd Paragraph

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-3, 5-13 and 20 are rejected as failing to define the invention in the manner required by 35 U.S.C. 112, second paragraph.

The claim(s) are narrative in form and replete with indefinite and functional or operational language. The structure which goes to make up the device must be clearly and positively specified. The structure must be organized and correlated in such a manner as to present a complete operative device. The claim(s) must be in one sentence form only. Note the format of the claims in the patent(s) cited.

5. Claims 1 and 7 were both amended to include the limitation of "said therapeutic protein drug does not normally provoke an immunological reaction" However, it is unclear how this limitation is a component of the indicator. Again, the claim must be drawn to the structure that makes up the device. The instant limitation is not a structure that makes up the device, and thus it is unclear what role it has in the claim.

This rejection is necessitated by amendment.

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6. Claim 5 recites the limitation "the relevant temperature" in line 5. There is insufficient antecedent basis for this limitation in the claim. This term is not mentioned previously in the instant claim, and it is not clear to what it is referring. It also is unclear when or under what conditions does the temperature become irrelevant.

Response to Arguments

7. The Applicant has responded to this rejection by stating that the specification discusses the word "relevant" and that its meaning is well understood. However, this rejection is not suggesting that the meaning of the word "relevant" is unknown, but the rejection is addressing to what relevant temperature is the term referring. By using the word "the" before "relevant temperature", the claim is suggesting that previously in the claim a relevant temperature was determined. However, this is not the case, thus the claim is indefinite.

This rejection is maintained from the previous office action.

8. Claim 5 recites the limitation "that period's length of time" in line 8. There is insufficient antecedent basis for this limitation in the claim. This term is not mentioned previously in the instant claim, and it is not clear to what it is referring.

Response to Arguments

9. The Applicant has responded to this rejection by stating that the incorporated references discuss the word "that period's length of time". However, this rejection is not suggesting that the meaning of the term is unsupported, but the rejection is addressing to what period of time is the term referring. By using the word "that" before

"period's length of time", the claim is suggesting that previously in the claim a time period was determined. However, this is not the case, thus the claim is indefinite.

This rejection is maintained from the previous office action.

10. The terms "small enough" or "often enough" in claim 5 are a relative terms which renders the claim indefinite. The terms "small enough" or "often enough" are not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Response to Arguments

11. The Applicant state that the incorporated reference teach how to determine "small enough" or "often enough". However, the Examiner must read the claims as broadly as reasonably possible in the absence of an explicit definition. The instant terms were not explicitly defined in the specification or the incorporated references. The incorporated reference may have included an embodiment of the term, however providing an embodiment of the term is not the same as defining the term. Thus the terms are relative terms which render the claim indefinite.

This rejection is maintained from the previous office action.

Claim Rejections - 35 USC § 112, 1st Paragraph

12. The following is a quotation of the first paragraph of 35 U.S.C. 112:

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The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

13. Claims 6 and 13 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention.

Instant claims 6 and 13 are drawn to the claimed device additionally monitoring motion, vibration, light or turbidity. The specification on page 18 indicates that these additional parameters may be included with the claimed device. However, neither the specification nor the claims teach what elements are required with the device in order to measure these additional parameters. Although there are different types of sensing devices known in the art, one of skill in the art must still incorporate these sensing devices with the claimed invention. Given that it is unclear what elements are required for the claimed device, and that one of skill in the art must still incorporate these sensing devices for the additional parameters with the claimed invention, one of skill in the art must perform undue experimentation to make the invention. Thus without further guidance from the specification, one of skill in the art cannot make the invention without undue experimentation.

Response to Arguments

14. The Applicant have responded to this rejection by stating that the sensors for motion, vibration, light or turbidity are well known in the art. While the sensors themselves are known individually, this rejection is also directed to how these sensors

are incorporated with the claimed invention. The Applicant has not addressed this point.

Claim Rejections - 35 USC § 102

15. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

16. Claims 1-3, 5, 7-12 and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Karr et al. (US 4,277,974).

The instant claims are drawn to a time-indicator device. Although the claims indicate that the device is used for monitoring a therapeutic protein drug, such intended use is not given patentable weight.

Regarding claims 1 and 7, Karr et al. teaches an electronic time temperature indicator device with a parameter (abstract) a means to integrate time and temperature, and indicator output means, and a time-temperature parameter setting means (abstract; column 6, lines 34-40). In instant claim 1 the limitations listed from lines 8 –16 and 20-25 and in instant claim 7 the limitations listed from lines 11-17 and 20-25 are all activities that occur outside the device. These activities are akin to a product by process claim that describes the parameter. As product by process claim, the Examiner must only find the product (parameter) to anticipate the limitation. Thus, the activities themselves are not given any patentable weight. Furthermore, in lines 1-4, the instant

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claim recites an intended use. This recitation is also not given patentable weight.

Claims 1 and 7 were also amended to include the limitation of "said therapeutic protein drug does not normally provoke an immunological reaction" This limitation is not drawn to the device itself and is not given patentable weight. Thus the instant claims are drawn to a time-temperature device with one time-temperature indication parameter as taught by Karr et al.

Regarding claim 2, 3, 8 and 20, Karr et al. disclose wherein their device is electronic (abstract) and is chemical (consumption of the electrode is a chemical process) (abstract) and has a visual display (abstract).

Regarding claim 5, Karr et al. disclose sampling temperature continuously (column 2, lines 5-31); computing a function to determine the impact of time and temperature (column 5, line 11- column 6, line 40); comparing the result of the function to a reference value (column 5, line 11- column 6, line 40); then generating a output for the fitness of the drug (column 4, lines 15-25).

Regarding claim 9, Karr et al. disclose wherein the device is programmed with time-temperature indication parameters (column 5, lines 11-40).

Regarding claim 10, Karr et al. teach having an integrated circuit chip (microprocessor) and power from a battery (column 3, lines 1-65).

Regarding claim 11, Karr et al. teach where the device indicates the percentage of remaining lifetime (for example, if rejected the remaining lifetime is zero) (column 4, lines 14-20).

Regarding claim 12, Karr et al. teach wherein the device is attached to a dispensing device (column 3, lines 52-68).

Response to Arguments

17. The Applicant has responded to this rejection by first stating that “immunological risk” is different from a “deterioration of a product”. First, the Examiner points out that the instant claims are drawn to a time-temperature device and the phrase “for the monitoring the immunological risk status” is viewed as the intended use of the device and is not given patentable weight. Secondly, a degraded protein can induce an immunological response. Although it is possible that a immunological risk may occur before a protein degrades, it is also possible that when a protein has degraded that protein will also have immunological risk. Thus determining if a protein has degraded also determines that a protein has an immunological risk. In this respect, Karr et al. anticipated the instant claims.

Secondly, the Applicant says that the immunological risk does not necessarily occur at “a rate approximately exponentially related to the temperature of the product” but may have a more complex temperature dependency. However, this limitation is not in the claims and thus cannot distinguish the claims from the prior art.

Finally, the Applicant says that Kerr et al.’s claims are different from his claims. However, the teachings of Kerr et al. are not limited to his claims, and the Examiner is free to use the teachings found throughout his patent.

This rejection is maintained from the previous office action and necessitated by amendment.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jerry Lin whose telephone number is (571) 272-2561. The examiner can normally be reached on 10:00-6:30, M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JL

MICHAEL BORIN, PH.D
PRIMARY EXAMINER

A handwritten signature in black ink, appearing to read 'Michael Borin', is written over the printed name and title.